

Applicants : BIANCHI, et al.  
U.S. Serial No.: 10/519,427  
Filed : December 22, 2004  
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#### **REMARKS**

Claims 1-18 are pending in this application. By this amendment Applicants have amended claims 1-8 to incorporate the suggestions of the Examiner to whom this application is assigned. Applicants have cancelled claims 9-18 without prejudice to pursue the subject matter in a future continuation or divisional application. Applicants have added new claims 19-26.

Support for new claims 19-26 may be found inter alia on page 29 line 20 to page 30 line 27.

Accordingly there is no issue of new matters and Applicants respectfully request the entry of this amendment. Upon entry, claims 1-8 and 19-26 will be pending and under examination.

#### **Information Disclosure Statement**

The Examiner has not considered Reference number 1 because the Examiner maintains that the reference should be considered by itself and Reference 11 because the reference lacked a publication date.

In response, Applicants maintain that reference number 1 should be considered a reference in itself. Furthermore, Reference number 11 (Exhibit 11 in the December 24, 2004) clearly indicates the publication date on the bottom left side of the page. Accordingly, Applicants hereby submit as **Exhibit A** (1 page) PTO Form 08B listing Exhibit 1 and Exhibit 11.

#### **Drawings**

The Examiner stated that the drawings are objected to as indicated in PTO form 948.

In response, Applicants submit replacement figures as **Exhibit B** (12 pages) in order to comply with the requirements of the USPTO.

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### **Title**

In accordance with the Examiners suggestions, Applicants have amended the title of the specification to clearly reflect the nature of the claimed subject matter.

### **Claim Objections**

The Examiner has objected to claim 1 for reciting non-elected subject matter. Furthermore, the Examiner has suggested that claims 6-8 be amended to improve the wording of the claims.

In response, Claim 1 has been amended to eliminate the reference to HMGB1 expressing vectors. Furthermore, Claims 6-8 have been amended to incorporate the word "to". Accordingly there is no issue of new matters and Applicants respectfully request the reconsideration and withdrawal of the above grounds of objection.

### **Claim Rejections - 35 USC § 112, second paragraph**

The Examiner has rejected claims 1-8 under 35USC 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. The Examiner stated that the intended meaning of "functional" is not clear. Furthermore, the Examiner states that the metes and bounds of the term "regeneration" are not defined by the claims.

Furthermore, the Examiner has rejected claims 1-8 as being indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is not clear what controls which of these limitations.

In response, but without conceding the correctness of the Examiners position and to expedite the prosecution of this application, Applicants have amended claims 1-8 by eliminating the term "functional" and introducing the term "tissue" before "regeneration". It is believed

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that the parts of HMGB1 that are included in the scope of amended claim 1 clearly refer to those having activity for the treatment of tissue damage etc. Accordingly, it is submitted that newly amended claims 1-8 will not raise the above rejections. Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

**Claim Rejections - 35 USC § 112, first paragraph**

**a. Enablement**

**1. General**

The Examiner rejected claims 1-8 under 35 USC § 112, first paragraph, because the specification, while being enabling for a composition comprised of [SIC] full length HMGB1 protein or tail-less HMGB1 (ABbt), does not reasonably provide enablement for compositions comprising any other functional parts of HMGB1 protein.

In response, Applicants respectfully traverse the above ground of rejection. Applicants' claim 1 recites:

A composition comprising an effective amount of the High Mobility Group One (HMGB1) protein or parts thereof for the treatment of tissue damage or to promote tissue repair and tissue regeneration.

The description on page 10 l. 12-17, page 26, l. 21-25, and Fig. 9 shows at least one example of a part of HMGB1 that exerts the same activity on tissue regeneration as the full HMGB1 (the tail less HMGB1, ABbt fragment of Fig. 9C).

Moreover it is clear and definite to an ordinary skilled artisan that the part or parts of the HMGB1 protein need to treat tissue damage or to promote tissue repair and tissue regeneration. Other simple experiments like trypsinization of the full protein will generate parts and determine where it is functional following the teachings of

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the specification. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

## 2. Cardiac Muscle or Mesoangioblast stem cell

Applicants maintain that the experiments performed pertaining to the Cardiac Muscle or Mesoangioblast stem cell would be applicable to other tissues or cells. Accordingly, to an ordinary skilled artisan, the invention is fully enabling. Accordingly Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

### b. Written description

The Examiner rejected claims 1-8 under 35 USC § 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response, Applicants respectfully traverse the above grounds of rejection. As conceded by the Examiner, page 5 of this office action, last paragraph, certain functional "parts" have been exemplified in the specification. Applicants maintain it is a routine experiment to generate other functional "parts". Accordingly, for an ordinary skilled artisan it is clearly demonstrated that the inventors are in possession of the claimed invention. In the molecular biology fields, the degeneracy of the genetic code is well-known. Similarly, the substitute of amino acids is well-known. Therefore it is clear that these changes will not reflect the possession of the claimed invention. Accordingly Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

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**Claim Rejections - 35 USC § 102**

The Examiner rejected claims 1-5 and 7-8 under 35 USC § 102 as being anticipated by Tracey et al.

In response, Applicants respectfully traverse the above grounds of rejection. Tracey, et al. is directed towards a different application or uses of the HMGB1 protein. Tracey et al. does not teach anything regarding the treatment of tissue damage, tissue repair, or tissue regeneration. Accordingly Tracey et al cannot anticipate the **EFFECTIVE AMOUNT** of the said protein or its functional parts. Accordingly Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

**Claim Rejections - 35 USC § 103**

The Examiner rejected claim 6 under 35 USC § 103 as being unpatentable by Tracey et al.

In response, response, Applicants respectfully traverse the above grounds of rejection. Tracey et al. does not teach anything regarding the treatment of tissue damage, tissue repair, or tissue regeneration. There is no motivation to use any effective amount for the claimed invention. Accordingly Tracey et al cannot render obvious the **EFFECTIVE AMOUNT** of the said protein or its functional parts.

Accordingly Applicants respectfully request the reconsideration and withdrawal of the above grounds of rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee besides the ONE HUNDRED AND TWENTY DOLLARS (\$120.00) extension of time fee is deemed necessary in connection with the filing of this Response. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Albert Wai Kit Chan 8/18/06  
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